

### REMARKS

Responsive to Action mailed April 11, 2006, the Applicants elect Group VI, inclusive of claims 25-31 and new claim 36, which depends from and therefore narrows claim 25.

The species elections as set out in the Action are reproduced below in small bold type. The Applicants' election is provided underneath each item.

**A.) A single specific GH/IGF-1 axis component. Applicants are further requested to elect a single specific selection of a GH/IGF-1 axis component OR a functional fragment thereof.**

The Applicants elect a Ghrelin receptor. Of the elected Group, claims 25-31 of and new claim 36 read on this species.

The Applicants also elect a the single axis component with traverse. There can be no undue burden to examine claims regarding both Ghrelin receptor and its fragments since it is likely that the same keywords (e.g., keywords relating to ghrelin receptor) and sequences would be used for both searches. The Action also does not offer any basis for why this election is required except at the most general level. However, dependent claims narrow the search required for examination of the base claim and therefore should not impose additional search requirements. In addition, the Action argues that the dependent claims are drawn to patentably distinct embodiments and therefore there is an undue burden. By this logic, the Office would always be able to restrict examination to a single independent claim and a single dependent claim thereby limiting examination to only a subset of the subject matter invented. Such action is clearly *ultra vires* since it is not authorized by § 121 and is contrary to § 131 of Title 35. Further, the Office has clearly abused its discretion by applying this argument here where the elected group includes only eight claims. The Office cannot justify this policy where the Office has adopted a fee structure that embraces twenty claims in a single application. Finally, this species election is likely to cause piecemeal and inefficient examination, causing prejudice to the Applicants and the public. For at least these reasons, the Applicants ask that the species election be withdrawn.

**B.) A single selection of contact a compound to a cell OR a non-human animal model.**

The Applicants submit that election of Group VI renders this requirement moot. However, to the extent that election is required, the Applicants elect a non-human animal model with traverse. Claims 25 and 27-31 of the elected Group and new claim 36 read on the elected species. There would be no undue burden to examine the claims with respect to both a cell and a non-human animal model. The Action does not offer any basis for why this election is required except at the most general level. However, dependent claims narrow the search required for examination of the base claim and therefore should not impose additional search requirements. In addition, the Action argues that the dependent claims are drawn to patentably distinct embodiments and therefore there is an undue burden. By this logic, the Office would always be able to restrict examination to a single independent claim and a single dependent claim thereby limiting examination to only a subset of the subject matter invented. Such action is clearly *ultra vires* since it is not authorized by § 121 and is contrary to § 131 of Title 35. Further, the Office has clearly abused its discretion by applying this argument here where the elected group includes only eight claims. The Office cannot justify this policy where the Office has adopted a fee structure that embraces twenty claims in a single application. Finally, this species election is likely to cause piecemeal and inefficient examination, causing prejudice to the Applicants and the public. For at least these reasons, the Applicants ask that the species election be withdrawn.

**C.) A single specific species of compounds. (Note: a selection of compounds based on molecular weight ranges does not satisfy the requirement. Examples of species could be antibodies, or aptamers, etc.)**

The Applicants elect a small organic molecule with traverse. Claims 25-31 of the elected Group and new claim 36 read on the elected species. The Action does not offer any basis for why this election is required except at the most general level. However, dependent claims narrow the search required for examination of the base claim and therefore should not impose additional search requirements. In addition, the Action argues that the dependent claims are drawn to patentably distinct embodiments and therefore there is an undue burden. By this logic, the Office would always be able to restrict examination to a single independent claim and a

single dependent claim thereby limiting examination to only a subset of the subject matter invented. Such action is clearly *ultra vires* since it is not authorized by § 121 and is contrary to § 131 of Title 35. Further, the Office has clearly abused its discretion by applying this argument here where the elected group includes only eight claims. The Office cannot justify this policy where the Office has adopted a fee structure that embraces twenty claims in a single application. Finally, this species election is likely to cause piecemeal and inefficient examination, causing prejudice to the Applicants and the public. For at least these reasons, the Applicants ask that the species election be withdrawn.

**D.) A single specific species of a disorder. (Note: Applicants are requested to selected a single specific disorder and further specify to which general category (e.g. neurological disorder) the selected specific disorder belongs.)**

The Applicants submit that election of Group VI renders this requirement moot. To the extent that an election is required, the Applicants elect a metabolic disorder, e.g., diabetes, with traverse. Claims 25-31 of the elected Group and new claim 36 read on the elected species. The Action does not offer any basis for why this election is required except at the most general level. However, dependent claims narrow the search required for examination of the base claim and therefore should not impose additional search requirements. In addition, the Action argues that the dependent claims are drawn to patentably distinct embodiments and therefore there is an undue burden. By this logic, the Office would always be able to restrict examination to a single independent claim and a single dependent claim thereby limiting examination to only a subset of the subject matter invented. Such action is clearly *ultra vires* since it is not authorized by § 121 and is contrary to § 131 of Title 35. Further, the Office has clearly abused its discretion by applying this argument here where the elected group includes only eight claims. The Office cannot justify this policy where the Office has adopted a fee structure that embraces twenty claims in a single application. Finally, this species election is likely to cause piecemeal and inefficient examination, causing prejudice to the Applicants and the public. For at least these reasons, the Applicants ask that the species election be withdrawn.

**E.) A single specific selection of a cell surface receptor OR a secreted molecule.**

The Applicants submit that election of Group VI renders this requirement moot. If the election is directed to the axis component, the Applicants select a cell surface receptor with traverse. Claims 25-31 of the elected Group and new claim 36 read on this species. To the extent that the election is directed at some other claim term, the Applicants are unable to determine which element in the claims of the elected group it is that the Examiner is referring to. Clarification is requested. The Applicants reserve all rights to traverse the requirement.

With respect to the traverse in the case that the election is directed to the axis component: the search required is likely to be the same or similar if the axis component is a cell surface receptor or a secreted molecule. The Action does not offer any basis for why this election is required except at the most general level. However, dependent claims narrow the search required for examination of the base claim and therefore should not impose additional search requirements. In addition, the Action argues that the dependent claims are drawn to patentably distinct embodiments and therefore there is an undue burden. By this logic, the Office would always be able to restrict examination to a single independent claim and a single dependent claim thereby limiting examination to only a subset of the subject matter invented. Such action is clearly *ultra vires* since it is not authorized by § 121 and is contrary to § 131 of Title 35. Further, the Office has clearly abused its discretion by applying this argument here where the elected group includes only eight claims. The Office cannot justify this policy where the Office has adopted a fee structure that embraces twenty claims in a single application. Finally, this species election is likely to cause piecemeal and inefficient examination, causing prejudice to the Applicants and the public. For at least these reasons, the Applicants ask that the species election be withdrawn.

**F.) A single specific and defined number of nucleotide mutations per nucleic acid sequence, (e.g. 4 mutations per nucleic acid sequence.)**

The Applicants submit that election of Group VI renders this requirement moot. To the extent an election is required, the Applicants are unable to determine which element in the claims of the elected group it is that the Examiner is referring to. Clarification is requested. The Applicants reserve all rights to traverse the requirement.

**G.) A single selection of an antagonist OR an agonist compound.**

The Applicants elect an antagonist. Claims 25-31 of the elected Group and new claim 36 read on the elected species.

**H.) A single specific selection of an in vitro contacting from a cell-based assay OR a cell-free assay.**

The Applicants elect a cell-based assay. Claims 25 and 26 of the elected Group and new claim 36 read on this species. There would be no undue burden to examine the claims with respect to both a cell-based and a cell-free assay. The Action does not offer any basis for why this election is required except at the most general level. However, dependent claims narrow the search required for examination of the base claim and therefore should not impose additional search requirements. In addition, the Action argues that the dependent claims are drawn to patentably distinct embodiments and therefore there is an undue burden. By this logic, the Office would always be able to restrict examination to a single independent claim and a single dependent claim thereby limiting examination to only a subset of the subject matter invented. Such action is clearly *ultra vires* since it is not authorized by § 121 and is contrary to § 131 of Title 35. Further, the Office has clearly abused its discretion by applying this argument here where the elected group includes only eight claims. The Office cannot justify this policy where the Office has adopted a fee structure that embraces twenty claims in a single application. Finally, this species election is likely to cause piecemeal and inefficient examination, causing prejudice to the Applicants and the public. For at least these reasons, the Applicants ask that the species election be withdrawn.

**I.) A single specific species of a subject.**

The Applicants elect a human subject with traverse. Of the elected Group, claims 25-31 and new claim 36 read on this species. This requirement is not understood since the elected claims do not use the term "subject." Further, the Action does not offer any basis for why this election is required except at the most general level and with no applicability to the claims in this group. The Action argues that the dependent claims are drawn to patentably distinct embodiments and therefore there is an undue burden. By this logic, the Office would always be able to restrict examination to a single independent claim and a single dependent claim, thereby

limiting examination to only a subset of the subject matter invented. Such action is clearly *ultra vires* since it is not authorized by § 121 and is contrary to § 131 of Title 35. Further, the Office has clearly abused its discretion by applying this argument here where the elected group includes only eight claims. The Office cannot justify this policy where the Office has adopted a fee structure that embraces twenty claims in a single application. Finally, this species election is likely to cause piecemeal and inefficient examination, causing prejudice to the Applicants and the public. For at least these reasons, the Applicants ask that the species election be withdrawn.

**J.) A single selection of an age-associated parameter.**

The Applicants submit that election of Group VI renders this requirement moot. This requirement is not understood since the elected claims do not use the term “age-associated parameter.” Clarification is requested. The Applicants reserve all rights to traverse the requirement.

**K.) A single selection of a direct antagonist of a positively acting component OR a direct agonist of an inhibitor component of the GH/IGF-1 axis.**

The Applicants submit that election of Group VI renders this requirement moot. This requirement is not understood since the elected claims do not use the terms mentioned in the requirement for election. Clarification is requested. The Applicants reserve all rights to traverse the requirement.

The Applicants note that upon allowance of a generic claim, the Applicants will be entitled to consideration of claims to additional species, which are written in dependent form or otherwise include all the limitations of an allowed generic claim, as provided by 37 CFR § 1.141.

The Applicants reserve the right to rejoin the remaining claims and to traverse the restriction between the remaining groups at a later date. No statement made herein is an admission that any claim or invention is not patentably distinct from another.

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Attorney's Docket No.: 13407-020001

Enclosed is a Five-Month Petition for Extension of Time. Please apply the fee to deposit account 06-1050, referencing Attorney's Docket Number 13407-020001.

Respectfully submitted,

Date: 11 October 2006

/RKTabtiang/

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